ATTORNEY DOCKET NO. 21101.0048U2
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	
	)	
Leppert, Mark F.	)	Art Unit: 1646
	)	
Application No. 10/585,717	)	Examiner: Pak, Michael P.
	)	
Int. Filing Date: January 21, 2005	)	Confirmation No. 4074
	)	
For: MUTANT SODIUM CHANNEL NAV 1.7 AND METHODS RELATED THERETO	)	

RESPONSE TO RESTRICTION REQUIREMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

BALLARD SPAHR ANDREWS & INGERSOLL, LLP
Customer Number 23859

Sir:

This is in response to the Office Action dated March 23, 2009, wherein restriction of the claims of the above-identified application is required.

Part I

The Office Action requires restriction to one of the following six groups of claims:

Group I: Claims 1-31, drawn to a method of characterizing a nucleic acid by identifying mutation;

Group II: Claim 32, drawn to a method of identifying a compound that modulates;

Group III: Claims 33-68, drawn to an isolated nucleic acid, expression vector, cell and method of making a mutant;

Group IV: Claim 69, drawn to a transgenic mouse;

Group V: Claims 70-81, drawn to an isolated peptide; and

Group V: Claims 70-81, drawn to an isolated peptide; and

Group VI: Claims 82-88, drawn to an antibody.

As required in response to the Restriction Requirement, Applicants provisionally elect Group I (claims 1-31) with traverse.

37 C.F.R. § 1.475 provides that national stage applications shall relate to one invention or to a group of inventions so linked as to form a single general inventive concept. Such inventions possess unity of invention. The Examiner proposes that the groups of inventions are not so linked as to form a single general inventive concept under PCT Rule 13.1. To support this proposition, the Examiner notes that whereas Group I is drawn to a method, Groups III-VI are products with materially different structures and functions. Likewise, Groups I and II are allegedly distinct from each other because they are drawn to processes having materially different process steps practiced for materially different purposes. Applicants respectfully disagree.

PCT Rule 13.2 states:

> The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. (*Emphasis added.*)

Applicants have discovered that specific sites in the $Na_v1.7$ gene are mutated in certain neurological disorders. Accordingly, Applicants have disclosed methods of characterizing mutant nucleic acid sequences that encode a Nav1.7 sodium channel alpha-subunit and the use of such nucleic acids to diagnose and treat disease neurological disorders such as seizures. As such, $Na_v1.7$ gene mutations within the specified regions represent a common special technical feature among the claims. For example, the isolated nucleic acids, vectors, cells, polypeptides, and

antibodies of Group III, V, and VI share this technical feature in that they are useful *inter alia* for detecting or investigating the specific $Na_v1.7$ mutations. Likewise, the transgenic mouse of claim 69 provides its contribution over the prior art in that has cells encoding mutant $Na_v1.7$ sodium channels, which results in increased seizure activity. Furthermore, the screening method of Group II uses cells encoding mutant $Na_v1.7$ genes to identify potential therapeutics of neurological disorders. Considered as a whole, all of the claims share the common technical feature of $Na_v1.7$ gene mutations within the specified regions which define a contribution which each of the claims makes over the prior art.

Applicants respectfully point out that the Examiner has not provided any evidence that any disclosure exists in the art that would destroy the novelty or inventive step of this common technical feature and thereby destroy the single inventive concept. Thus, the Examiner has not met the burden for establishing a lack of unity of invention and the restriction is improper.

Applicants also traverse the restriction requirement as currently set forth for the following reasons. To be valid, a restriction requirement must establish both that (1) the "inventions" are either independent or distinct, and (2) that examination of more than one of the "inventions" would constitute a burden to the Examiner. M.P.E.P. § 803 provides:

> If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions. (*Emphasis added.*)

Applicants note that the restriction requirement does not provide sufficient basis to indicate that examination of more than one of the "inventions" would overly burden the Examiner. Accordingly, for this additional reason, there is no basis for maintaining the restriction requirement.

Moreover, Applicants respectfully assert that restriction of the claims as set forth by the Examiner would be contrary to promoting efficiency, economy and expediency in the Patent Office and further point out that restriction by the Examiner is discretionary (M.P.E.P. § 803.01). Thus, Applicants respectfully request that all of the claims of this application be examined together. Consequently, reconsideration and modification or withdrawal of the restriction requirement is requested.

Part II

The Office Action requires restriction to "one sequence of SEQ ID NO:" Applicants recite amino acid sequences specific for each of the specified $Na_v1.7$ gene mutation, e.g., SEQ ID NOs:2-7 for each of I62V, P149Q, N641Y, K655R, I739V, and L1123F mutations. Applicants also provide amino acid fragments each of these mutations, i.e., SEQ ID NOs:32-37. These sequences are compared to the wildtype amino acid sequence SEQ ID NO:38. Applicant further provides primer pair sequences for detecting each of these mutations, i.e., SEQ ID NOs:20-31 (see Part III below). As such, Applicants understand this requirement to be an extension of Part IV below, i.e., an election of a specific $Na_v1.7$ gene mutation with its corresponding SEQ ID NOs. Applicants note, however, that except for the primer sequences, which are the subject of Part III, these SEQ ID NOs are not recited in Group I claims.

Nevertheless, if Group III claims are rejoined and examined, Applicants elect SEQ ID NO:4 (claims 45-50 relating to residue 641) with traverse. Moreover, if Group V is rejoined and examined, Applicants also respectfully requests that both SEQ ID NO:4 (claim 74) and SEQ ID NO:34 (claim 75) be examined since SEQ ID NO:34 is merely a fragment of SEQ ID NO:4.

Part III

The Office Action requires restriction to a single primer sequence. Applicants elect SEQ ID NOs:24 and 25 (claim 26) with traverse.

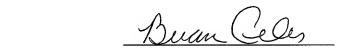
Part IV

The Office Action requires restriction to a single mutant type. Applicants elect amino residue 641 (claims 1, 8-10, 19-31 for Group I) with traverse.

Conclusion

Favorable consideration of claims 1-88 is earnestly solicited. It is believed that no fee is due with this submission. However, the Commissioner is hereby authorized to charge any fees which may be required to Deposit Account No. 14-0629.

Respectfully submitted,



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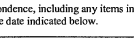
Signature		Date	4-20-2009